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(71) Applicant (for all designated States except US): WYETH HOLDINGS CORPORATION [US/US]; 5 Giralda Farms, Madison, NJ 07940 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): SMITH, Larry [US/US]; 11410 Turtleback Lane, San Diego, CA 92127 (US). CASSETTI, Maria, Cristina [IT/US]; 8217 Scotch Bend Way, Potomac, MD 20854 (US). MCELHINEY, Susan, P. [US/US]; P.O. Box 1039, Hillburn, NY 10931 (US). PULLEN, Jeffrey, K. [US/US]; c/o Wyeth Research Building, 401 N. Middletown Road, Pearl River, NY 10965 (US).

(74) Agents: FEHLNER, Paul, F. et al.; Darby & Darby, P.C., P.O. Box 5257, New York, NY 10150-5257 (US).

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(54) Title: HUMAN PAPILLOMAVIRUS POLYPEPTIDES AND IMMUNOGENIC COMPOSITIONS

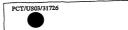
(57) Abstract: The present invention provides immunogenic and pharmaceutical compositions for the treatment and prevention of human papillomavirus (HPV)-associated cancers and in particular, cervical cancer. In particular, this invention relates to fusion proteins, and the nucleic acids encoding these fusion proteins, used to generate immune responses against HPV. Specifically, this invention provides for fusions of HPV E6 and E7 in which the E6 and/or E7 contains one or more mutations. These mutations abrogate the transformation activity of these oncogenic proteins and, thus, confer safety to the E6/E7 fusions. In addition, these fusions maintain or increase the immunogenic efficacy of E6 and E7. Any gene or protein delivery method can be used to deliver or package the immunogenic compositions of the present invention.





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INTERNATIONAL SEARCH REPORT



BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-4, 11, 12, 16 and 21, drawn to human papillomavirus E6 and E7, and a method of inducing immune response. (1st product and method)

Group II, claim(s) 5-10, 13, 19, 20, drawn to isolated nucleic acid, expression vector and method of preventing cervical cancer. (2nd product and method)

Group III, claim(s) 14, and 15, drawn to a recombinant virus. (3rd product)

Group IV, claim(s) 17, and 18 drawn to methods of treating and preventing cervical cancer. (3rd method)

Group V, claim(s) 22, drawn to isolated polypeptide. (within the scope of SEQ ID NO: 3) (4th product)

Group VI, claim(s) 23, 25, drawn to isolated nucleic acid. (within the scope of SEQ ID NO: 3) (5th product)

Group VII, claim(s) 24, 26, drawn to isolated nucleic acid. (within the scope of SEQ ID NO: 4) (6th product)

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

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SEQ ID NO: 5, 9, 11, as they apply to Group V.
SEQ ID NO: 5, 9, 11, as they apply to Group VI. SEQ ID NO: 6, 10, 12, as they apply to Group VII.
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The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group I is known in the prior art as evidence by Edwards et al (US Patent No. 6,004,557) wherein the patent teaches the fusion protein of E6 and E7 human papillomavirus (see claim 1). The cited evidence proves that the technical feature of Group I does not make a contribution over the prior art. Thus, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the sequences listed confer different structure and presumably different effect.

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

Inte	tional application No.
	US03/31726

Box I Observations where certain claims were found unsearchal	le (Continuation of Item 1 of first sheet)
This international report has not been established in respect of certain claim	ns under Article 17(2)(a) for the following reasons:
Claim Nos.: because they relate to subject matter not required to be search.	hed by this Authority, namely:
Claim Nos.: because they relate to parts of the international application such an extent that no meaningful international search can be	hat do not comply with the prescribed requirements to e carried out, specifically:
Claim Nos.: because they are dependent claims and are not drafted in ac 6.4(a).	
Box II Observations where unity of invention is lacking (Cont	nuation of Item 2 of first sheet)
This International Searching Authority found multiple inventions in this is Please See Continuation Sheet 1. As all required additional search fees were timely paid by	
As all required additional search less were unany parts by searchable claims. As all searchable claims could be searched without effort payment of any additional fee. As only some of the required additional search fees were report covers only those claims for which fees were paid,	ustifying an additional fee, this Authority did not invite limely paid by the applicant, this international search
No required additional search fees were timely paid by d is restricted to the invention first mantioned in the claims	e applicant. Consequently, this international search report; it is covered by claims Nos.: 1-4,11,12,16 and 21
Remark on Protest The additional search fees were accome No protest accompanied the payment of	

Form PCT/ISA/210 (continuation of first sheet(1)) (July 1998)

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Continuation of B. FIELDS SEARCHED Item 3: MEDLINE, BIOSIS, NPL, WEST, DERWENT, IPA, EPA search terms: Papillomavirus, E?, E6, E7, immune response, mutant?

Form PCT/ISA/210 (second sheet) (July 1998)